

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Marin et al.
Serial No. : Not Yet Assigned Authorized Officer: Not Yet Assigned
Filed : January 2, 2002 Group Art Unit: Not Yet Assigned
For : USE OF CORTISOL ANTAGONISTS IN THE TREATMENT
FOR HEART FAILURE

INFORMATION
DISCLOSURE
STATEMENT

I hereby certify that this paper is being deposited with the United States
Postal Service as Express Mail No. ET 544 763 265 US addressed to:
Commissioner for Patents, Arlington, VA 22202

December 28, 2001
Date of Deposit

Rochelle K. Seide
Attorney Name

Rochelle K. Seide
Signature

32,200
PTO Registration No.

December 28, 2001
Date of Signature

Hon. Commissioner for Patents and Trademarks
U.S. Patent and Trademark Office
P.O. Box 2327
Arlington, VA 22202

Sir:

Pursuant to the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants respectfully
request that the references relating to the above-mentioned application listed herein be

made of record in the U.S. Patent and Trademark Office. The referenced citations are listed in the accompanying PTO Form 1449 and copies of the references are enclosed.

1. International Patent Application No. PCT/FR98/02302 by Antonov for "Use of antifungal agents for treating scleroses" filed 27 October 1998 and published as WO 00/24402 on 4 May, 2000.
2. International Patent Application No. PCT/SE99/01713 by Uvnäs-Moberg *et al.* for "Use of substances with oxytocin activity in order to create cell regeneration" filed 27 September 1999 and published as WO 00/18424 on 6 April 2000.
3. Faggiano P, D'Aloia A, Gualeni A, Giordano A. Hemodynamic profile of submaximal constant workload exercise in patients with heart failure secondary to ischemic or idiopathic dilated cardiomyopathy. *Am J Cardiol* 1998 Feb 15;81(4):437-442.
4. Ganiats TG, Browner DK, Dittrich HC. Comparison of Quality of Well-Being scale and NYHA functional status classification in patients with atrial fibrillation. New York Heart Association. *Am Heart J* 1998 May;135(5 Pt 1):819-824.
5. Scheuer DA, Mifflin SW. Chronic cortisone treatment increases myocardial infarct size in rats with ischemia-reperfusion injury. *Am J Physiol* 1997 Jun;272(6 Pt 2):R2017-2024.
6. Spitz IM, Bardin CW. Mifepristone (RU 486)--a modulator of progestin and glucocorticoid action. *N Engl J Med* 1993 Aug 5;329(6):404-412.

531 Rec'd PCT 28 DEC 2001

7. Rotstein DM, Kertesz DJ, Walker KA, Swinney DC. Stereoisomers of ketoconazole: preparation and biological activity. J Med Chem 1992 Jul 24;35(15):2818-2825.
8. Dvortsin GF. Use of a synthetic opioid for the reversal of stress-induced damage of the myocardium and gastric mucosa in severe thermal trauma [In Russian]. Kardiologiia 1989 Sep;29(9):81-83.
9. Aggermaes H, Kirkegaard C, Magelund G. The effect of sodium valproate on serum cortisol levels in healthy subjects and depressed patients. Acta Psychiatr Scand 1988 Feb;77(2):170-174.
10. Slowinska-Srzednicka J, Zgliczynski S, Soszynski P, Pucilowska J, Wierzbicki M, Jeske W. Effect of clonidine on beta-endorphin, ACTH and cortisol secretion in essential hypertension and obesity. Eur J Clin Pharmacol 1988;35(2):115-121.
11. Legros JJ, Chiodera P, Geenen V, von Frenckell R. Confirmation of the inhibitory influence of exogenous oxytocin on cortisol and ACTH in man: evidence of reproducibility. Acta Endocrinol (Copenh) 1987 Mar;114(3):345-349.
12. United States Patent No. 4,603,141 by Giles for "Oral Clonidine Treatment of Congestive Heart Failure" issued July 29, 1986.
13. Loose DS, Stover EP, Feldman D. Ketoconazole binds to glucocorticoid receptors and exhibits glucocorticoid antagonist activity in cultured cells. J Clin Invest 1983 Jul;72(1):404-408.

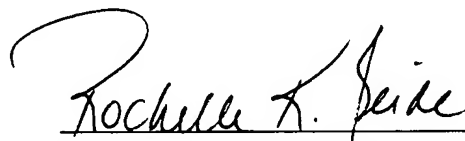
14. Stubbs WA, Delitala G, Jones A, Jeffcoate WJ, Edwards CR, Ratter SJ, Besser GM, Bloom SR, Alberti KG. Hormonal and metabolic responses to an enkephalin analogue in normal man. Lancet 1978 Dec 9;2(8102):1225-1227.

Identification of the above-listed references is not to be construed as an admission of the Applicants or the attorneys of the Applicants that such references are available as "prior art" against the subject application.

Applicants respectfully request that the Examiner review the foregoing references and that the references be made of record in the file history of the above-mentioned application.

Please charge our Deposit Account No. 02-4377 if there is any additional fee required. Two copies of this communication are enclosed.

Respectfully submitted,


Rochelle K. Seide, Ph.D.
Patent Office Reg. No. 32,200
Attorney for Applicants
(212) 408-2626

Enclosures